K072523

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

Submitter's name:	Diazyme Laboratories
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	JAN 22 2008
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Date the Summary was Prepared:	August 22, 2007
Name of the Device	Diazyme LDL-Cholesterol Reagent
Trade Name:	Diazyme LDL-Cholesterol Reagent
Common/Usual Name	Lipoprotein Test System
Device Classification Name	Low Density Lipoprotein Cholesterol Reagent
Product code:	LBR, JIS, JIX
Submission Type	510k
Regulation Number	862.1475
Device Class	II
Predicate Device:	For the Lipoprotein test system, we are claiming equivalence [807.92(a) (3) to N-GENEOUS LDL CHOLESTEROL REAGENT (k971573) manufactured by Genzyme Diagnostics

Substantial Equivalence Information

1. **Predicate device name(s):**

   Genzyme N-Geneous LDL Cholesterol Reagent

2. **Predicate 510(k) number(s):**

   K971573

3. **Comparison with predicate:**

Indications for Use

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
The Diazyme LDL-Cholesterol Assay is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.	For the direct, quantitative measurement of low density lipoprotein cholesterol (LDL-C) concentration in human serum or plasma.	Same

Principle

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol-methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents. LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER). The enzymes selectively react with HDL to produce H_2O_2 which is detected through a Trinder reaction.	This method is in a two reagent format and depends on the properties of a unique detergent. This detergent (Reagent 1) solubilizes only the non LDL lipoprotein particles. The cholesterol released is consumed by cholesterol esterase and cholesterol oxidase in a non color forming reaction. A second detergent (Reagent 2) solubilizes the remaining LDL particles and a chromogenic coupler allows for color formation. The enzyme reaction with LDL-C in the presence of the coupler produces color that is proportional to the amount of LDL cholesterol present in the sample.	Similar

Test Objective

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
For the in vitro quantitative determination of low density lipoprotein cholesterol in human serum or plasma.	For the direct, quantitative measurement of low density lipoprotein cholesterol (LDL-C) concentration in human serum or plasma.	Same

Type of Test

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
Quantitative	Quantitative	Same

Specimen Type

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
Human serum or plasma	Human serum or plasma	Same

Product Type

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent	Equivalency
Calibrator, Reagent, Instrument	Calibrator, Reagent, Instrument	Same

Performance

Diazyme LDL-Cholesterol Reagent	Genzyme N-Geneous LDL Cholesterol Reagent
Reportable Range: Serum: **2.04 - 250 mg/dL** Precision/Serum: Within Run: **0.7% -1.0%** Total: **1.4%–1.6%** Accuracy/Serum: Correlation Coefficient: **0.9804** Slope/Intercept: **y = 1.0883x + 0.6078 mg/dL**	Reportable Range: Serum: **6.6- 992mg/dL** Precision/Serum: Within Run: **0.62% -0.73%** Total: **1.73%–2.27%** Accuracy/Serum: Correlation Coefficient: **0.96** Slope/Intercept: **y = 0.95x + 3.02mg/dL**

Calibrator Comparison

Diazyme LDL Cholesterol Calibrator	Genzyme N-Geneous LDL Cholesterol Calibrator	Equivalency
Lyophilized form	Lyophilized form	Same
LDL Cholesterol calibrator is traceable to NIST SRM 1915b.	LDL N-Geneous calibrator is traceable to the CDC HDL reference method**.	Same

** National Reference System for Cholesterol. CRMLN LDL Cholesterol Protocol, May 2004.

Rationale for Considering the Device Substantially Equivalent to Devices Approved for Interstate Commerce

Genzyme N-geneous LDL Cholesterol Reagent (k971573) was selected for comparing serum samples with to the results generated by Diazyme LDL-Cholesterol Reagent. Detailed performance characteristics and comparison analysis are given in this filing and demonstrate substantial equivalence to predicate device that is currently being legally marketed.

The Diazyme LDL-Cholesterol Reagent is similar to the approved predicate test. The minor differences in the performances of the tests should not affect the safety and effectiveness of the Diazyme LDL-Cholesterol Reagent and offers users an *in-vitro diagnostic* device to measure LDL Cholesterol in human serum or plasma.

In summary, the dissimilar features between the Diazyme LDL-Cholesterol Reagent and devices currently legally marketed do not affect the safety or effectiveness of the device. This is supported by the accuracy data comparing serum sample values obtained using the Diazyme LDL-Cholesterol Reagent with those obtained using the predicate device, Genzyme N-geneous LDL Cholesterol Reagent (k971573).

Description of the Device

The assay is based on a modified polyvinyl sulfonic acid (PVS) and polyethylene-glycol methyl ether (PEGME) coupled classic precipitation method with the improvements in using optimized quantities of PVS/PEGME and selected detergents. LDL, VLDL, and chylomicron (CM) react with PVS and PEGME and the reaction results in inaccessibility of LDL, VLDL and CM by cholesterol oxidase (CHOD) and cholesterol esterase (CHER), whereas HDL reacts with the enzymes. Addition of R2 containing a specific detergent releases LDL from the PVS/PEGME complex. The released LDL reacts with the enzymes to produce H_2O_2 which is quantified by the Trinder reaction.

$$\text{HDL + LDL + VLDL + CM} \xrightarrow[\text{PEGME}]{\text{PVS}}$$

$$\text{HDL + (LDL + VLDL + CM) · PVS/PEGME}$$

$$\text{HDL + CHOD + CHER} \longrightarrow \text{Fatty Acid + } H_2O_2$$

$$\text{(LDL + VLDL + CM)· PVS/PEGME} \xrightarrow{\text{Detergent}}$$

$$\text{LDL + (VLDL + CM) · PVS/PEGME}$$

$$\text{LDL + CHOD + CHER} \longrightarrow \text{Fatty acid + } H_2O_2$$

$$2H_2O_2 + \text{4-AA+TODB} \xrightarrow{\text{Peroxidase}} \text{Quenone + 5 } H_2O \quad (\lambda_{max}=560\text{nm})$$

Intended Use of the Device:

The Diazyme LDL-Cholesterol Reagent is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.

Performance Characteristics

Diazyme LDL-Cholesterol Reagent is a homogeneous two-reagent enzymatic assay. The results are obtained in 10 minutes by measuring absorbance at 600 nm. The linearity of the assay is from 1.64 - 830 mg/dL for serum samples. The assay offers excellent precision as shown in the tables below:

Serum Testing	**Level 1 95mg/dL LDL**	**Level 2 146mg/dL LDL**	**Level 3 210mg/dL LDL**
Within-Run Precision	$C_V\% = 1.0\%$	$C_V\% = 0.8\%$	$C_V\% = 0.7\%$
Total Precision	$C_V\% = 1.6\%$	$C_V\% = 1.5\%$	$C_V\% = 1.4\%$

In method comparison studies, samples tested with Diazyme LDL-Cholesterol Reagent showed good correlation with Genzyme N-geneous LDL Cholesterol Reagent (k971573) with correlation coefficients of 0.996 for serum samples.

We have conducted interference studies by spiking normal pooled human serum samples with substances normally present in serum or plasma and found less than 10% interference at the indicated concentrations.

Interference Study	
Substance	**Concentration**
Triglycerides	1000 mg/dL
Ascorbic acid	10 mmol/L
Bilirubin	40 mg/dL
Bilirubin Conjugated	40 mg/dL
Hemoglobin	1000 mg/dL

Conclusion: Comparison analysis presented in this 510k submission filing in the comparison section, together with linearity, precision and interference and other detailed studies, demonstrates that the Diazyme LDL-Cholesterol Reagent has excellent accuracy and is safe and effective. There is no significant deviation between the results obtained by Diazyme LDL-Cholesterol Reagent and the legally marketed predicate device (k971573) when testing clinical patient samples and is therefore substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 22 2008

General Atomics
Diazyme Laboratories Division
c/o Mr. Charles Yu
12889 Gregg Court
Poway, CA 92064

Re: k072523
Trade/Device Name: Diazyme LDL-Cholesterol Reagent
Regulation Number: 21 CFR§862.1475
Regulation Name: Lipoprotein Test System
Regulatory Class: Class I
Product Code: LBR, JJX
Dated: November 12, 2007
Received: November 15, 2007

Dear Mr. Yu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0490. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address at http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Jean M. Cooper, M.S., D.V.M.

Jean M. Cooper, M.S., D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
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Enclosure

Indications for Use

510(k) Number: K 072523

Device Name: Diazyme LDL-Cholesterol Reagent

Indications for Use: The Diazyme LDL-Cholesterol Assay is intended for the in vitro quantitative determination of Low Density Lipoprotein Cholesterol in human serum or plasma. The reagents can assist in the diagnosis and treatment of patients at risk of developing coronary heart disease. Elevated LDL cholesterol is the primary target of cholesterol-lowering therapy.

Calibrator: For calibration of the Diazyme LDL-Cholesterol Reagent Assay in serum or plasma.
For In Vitro Diagnostic Use

Controls: To monitor the performance of Diazyme LDL-Cholesterol Reagent.
For In Vitro Diagnostic Use

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Carol C Benson
~~Concurrence of CDRH~~, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

510(k) Summary

Office of In Vitro Diagnostic Device
Evaluation and Safety

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